PATENT
Docket No. 273012013100

CERTIFICATE OF MAILING BY "FIRST CLASS MAIL"

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on April 02, 2003.

Box Issue Fee

Diane Blevins

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Janice NORTH, et al.

Serial No.: 10/199,662

Filing Date: July 19, 2002

For: TREATMENT OF MACULAR EDEMA

Examiner: Henley III, R.

Group Art Unit: 1614

DECLARATION OF JANICE NORTH, PETER HNIK, AND H. ANDREW STRONG UNDER 37 C.F.R. § 1.131

We, Janice North, Peter Hnik, and H. Andrew Strong, declare as follows:

1. We are Canadian citizens (with Janice North also being a British citizen) and co-inventors of the subject matter claimed in the above identified application. Our work on the claimed subject matter occurred in Canada.

2. Prior to 15 March 2001, and after 8 December 1993[1], we conceived of treating diabetic macular edema (DME) using photodynamic therapy (PDT) with benzoporphyrin derivative ring A monoacid (BPD-MA).

[1] The date on or after which an applicant can establish a date of completion of an invention in Canada, a NAFTA member country.

sd-133458

3. Attached hereto as Exhibit A is the first page from a draft Phase I protocol document prepared by Peter Hnik describing the use of BPD-MA for clinical use in the treatment of DME with PDT. Prior to 15 March 2001, this protocol document was sent to Jennifer Kaufman-Shaw[2] by Peter Hnik to assist her in the preparation of a patent application. This led to the filing of U.S. Provisional Patent Application 60/306,731 on 20 July 2001. The instant application claims benefit of priority from U.S. Provisional Patent Application 60/306,731.

4. During the time period between 15 March 2001 and 20 July 2001, and while Jennifer Kaufman-Shaw prepared a patent application for filing, we continued our efforts to reduce the invention to practice. Attached hereto as Exhibit B (two sheets) are the cover and first page from a draft of Clinical Study Protocol BPD OCR 016 which reflects our efforts to reduce the invention to practice. As indicated on the first sheet of Exhibit B, the draft is directed to a Phase I/II (as opposed to the Phase I only protocol reflected in Exhibit A) study on the treatment of diabetic macular edema with Verteporfin for Injection (BPD-MA). The second sheet of Exhibit B indicates that the document was prepared in part by Janice North and Peter Hnik. The draft was completed after the filing of U.S. Provisional Patent Application 60/306,731 on 20 July 2001.

We further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States

---

[2] Senior Director, Intellectual Property, at QLT Inc., assignee of the instant application.

Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Executed in British Columbia, Canada on the dates as indicated below.

Janice North

Date: 22 April 2003

Peter Hnik

Date: April 22/2003

H. Andrew Strong

Date: April 22/2003

EXHIBIT "A"

A Phase I Study of the Treatment of Diabetic Macular Edema Using Photodynamic Therapy (PDT) with Liposomal BPD-MA (Verteporfin)

1. Drug

Liposomal BPD-MA (verteporfin) for clinical use

2. Indication

Treatment of diabetic macular edema with preserved visual acuity with Photodynamic Therapy (PDT)

3. Clinical Phase

Clinical phase I study – to accumulate short-term safety and preliminary efficacy data

4. Study Results Use

If safety and preliminary efficacy are clinically demonstrated, a phase II clinical trial will follow with longer, more detailed follow-up assessments to determine efficacy and long-term safety of the procedure.

[redacted]

Clinical Study Protocol – BPD OCR 016

Visudyne™ (Verteporfin for Injection)

A Placebo-Controlled, Single-Masked Phase I/II Study of the Effect of Visudyne™ Therapy in Diabetic Macular Edema Secondary to Diabetes Mellitus

SHORT TITLE:
Visudyne In Treatment of Diabetic Macular Edema (VIDME)

PROTOCOL (Draft 1): [redacted]

CONFIDENTIAL

QLT Inc.
887 Great Northern Way
Vancouver, British Columbia
Canada V5T 4T5

Novartis Ophthalmics AG
Grenzstrasse 10
CH-8180 Bülach
Switzerland

Novartis Ophthalmics, Inc.
11695 Johns Creek Parkway
Duluth, Georgia
USA 30097

EXHIBIT "B"
(Sheet 2 of 2)

SIGNATURE PAGE

Protocol Number: BPD OCR 016

Title of Protocol: A Placebo-Controlled, Single-Masked Phase I/II Study of the Effect of Visudyne™ Therapy in Diabetic Macular Edema Secondary to Diabetes Mellitus

Prepared by:

[redacted] Date

Jan North
Manager, Clinical Research
Date

Peter Hnik, MD, MHSc
Medical Advisor
Date

Approved by:

[redacted] Date

[redacted] Date

[redacted] Date

[redacted] Date